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Dräger medical
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3.0 510(k) Summary

as required per 807.92(c)

3.1 Name of Submitter, Contact Information and Date Summary Prepared

Name	Draeger Medical Systems, Inc.
Address:	6 Tech Drive, Andover, MA 01810
Official Contact:	Pradeep Gupta, Manager Regulatory Affairs
Telephone:	(978) 379-8219
Fax:	(978) 379-8331
Date Prepared:	November 5, 2008

3.2 Device Trade Name, Common Name& Regulation:

Trade Name:	Infinity Nellcor OxiMax SmartPod
Common Name:	Pulse Oximeter
Classification Name	Oximeter
Regulation Number:	21 CFR 870.2700

3.3 Device Code & Class:

Classification Code:	DQA
Class:	Class II

3.4 Legally Marketed Equivalent Device Names

Substantial equivalence is claimed to the Infinity Masimo SET® SpO2 pod 510(k) submission # K061329.

3.5 Device Description:

The Infinity Nellcor OxiMax SmartPod is an addition to Draeger Medical System's Infinity patient monitoring series that provides continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, pediatric, and neonatal patients. The Infinity Nellcor OxiMax SmartPod is manufactured by Draeger Medical Systems, Inc. and contains the Nellcor OxiMax Pulse Oximeter's Nell-1 circuit board with Nellcor's SpO2 measurement algorithm.

The Infinity Nellcor OxiMax SmartPod works as a component of the Infinity Patient Monitoring series and does not function on its own. The In-

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finity Nellcor OxiMax SmartPod is connected externally via RS232 using X8 connector on the Infinity Delta series monitors. The Infinity Nellcor OxiMax SmartPod is powered by the patient monitor. A Nellcor OxiMax Pulse Oximetry sensor is attached to a patient finger and one end of the patient cable is connected to the sensor and the other end connected to the Infinity Nellcor OxiMax SmartPod. The monitor will begin continuously displaying the patient's pulse rate and SpO2 value. Hi/Low SpO2 and pulse rate alarm limits, alarms, trends, and status messages are all controlled by the bedside monitor.

3.6 Intended Use:

The Infinity Nellcor OxiMax SmartPod is intended to provide continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, pediatric, and neonatal patients. The Infinity Nellcor OxiMax SmartPod is intended to be used by Healthcare Providers, i.e. Physicians, Nurses, and Technicians in the hospital and hospital type facilities.

3.7 Comparison to Predicate Device:

Similar to Infinity Masimo SET® SpO2 pod, the Infinity Nellcor OxiMax SmartPod provides continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, pediatric, and neonatal patients.

3.8 Assessment of non-clinical performance data for equivalence:

The Infinity Nellcor OxiMax SmartPod was tested in accordance with the applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate device. Verification and validation testing performed indicate that the software modifications described in this submission are as safe and effective as previous versions and have not altered the fundamental technology of the device(s). Additionally, testing demonstrates that SpO2 and pulse rate values calculated by the third party (OEM) device (Nellcor OxiMax Pulse Oximeter N-600x) are identical to the values displayed on the Draeger Medical Infinity Delta series monitors.

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3.9 Biocompatibility:

The biocompatibility of the sensors is provided by the sensor manufacturer Nellcor Puritan Bennett, Inc. (K060576)

3.10 Sterilization:

Not Applicable

3.11 Standards and Guidance:

Electrical Safety:	IEC 60601-1: Medical electrical equipment general requirements for safety and essential performance
	ISO 9919 (2005): Medical electrical equipment – particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
Guidance Documents:	"Deciding When to Submit a 510(k) for a Change to an Existing Device" released on January 10, 1997
	Draft Guidance for Industry and FDA Staff- "Pulse Oximeters – Premarket Notification Submissions [510(k)]" released on July 19, 2007

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Pradeep Gupta
Manager Regulatory Affairs
Draeger Medical Systems, Incorporated
6 Tech Drive
Andover, Massachusetts 01810

NOV 2 6 2008

Re: K082888
Trade/Device Name: Infinity Nellcor OxiMax SmartPod
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 6, 2008
Received: November 7, 2008

Dear Mr. Gupta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082888

Device Name: Infinity Nellcor OxiMax SmartPod

The Infinity Nellcor OxiMax SmartPod is intended for use under the direct supervision of a licensed healthcare practitioner (i.e. Physicians, Nurses, and Technicians). It is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor).

The Infinity Nellcor OxiMax SmartPod is indicated for use with adult, pediatric, and neonatal patients.

The Infinity Nellcor OxiMax SmartPod and accessories are indicated for use with patients who are well or poorly perfused in hospitals and hospital type facilities.

The Infinity Nellcor OxiMax SmartPod is not compatible for use in home care environment and in hospitals where CT, Hyperbaric chambers and MRI equipment are in use.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

vision Sign-Off)
ision of Anesthesiology, General Hospital
ction Control, Dental Devices

(k) Number: K082888